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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,240	11/30/2001	Wen Liang Yan	0249-0001	2508

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EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	**PAPER NUMBER**
1632	

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10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,240	YAN ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-82,84-88,90 and 92-95* is/are pending in the application.

4a) Of the above claim(s) *7-69, 74, 76-79, 81, and 85-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-73,75,80,82,84,90 and 92-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response received on 08/10/07 has been entered. No claim was amended. Pending claims under examination were filed 01/29/2007. Claims 1-6, 83, 89, and 91 are cancelled. Claims 7-82, 84-88, 90, and 92-95 are pending.

Claims 7-69, 74, 76-79, 81, and 85-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 70-73, 75, 80, 82, 84, 90, 92-95 are currently under examination

This application 09/997,240 filed on 11/30/2001 claims benefit of 60/253,943 filed on 11/30/2000.

Claim Objections

1. Claims 70 and 72 are objected to because of the following informalities: step (b) of claim 70 and step (a) of claim 72 recite both "germ cell" and "the extrusion of the second polar body during oogenesis". It is noted that "the extrusion of the second polar body during oogenesis" is specific for oocytes, however, the recited "germ cell" is broader than oocyte. and thus the terminology is inconsistent. Relevant to this issue, it is not clear in claim 70 as written whether the oocyte used in step (b) is the same as that of step (a). Appropriate correction is required.

2. Claim 70 remains objected to under 37 CFR 1.75 as being a substantial duplicate of claims 72, 73, 75, 80, 82, and 90. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The phrase "parthenogenetically created" recited in claims 70, 72, 73, 75, 80, and 90 is considered as part of the processes of a method of making the recited stem cell, and the processes of a method of making is not given patentable weight. Therefore, independent claims 70, 72, 73, 75, 80, and 90 are substantially duplicated. In this regard, applicants attention is drawn to the following statements: When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983), and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

In the response filed by Applicant on 08/10/2007, Applicant addressed this objection along with other rejections as elaborated below.

Applicant's arguments

With regard to whether claim 70 being a substantial duplicate of claims 72, 73, 75, 80, 82, and 90, Applicant argues that the instant invention serves as a typical example of a situation where a product resists by other than the process by which it is made and it is clearly erroneous for the Examiner to dismiss a phrase which breathes life and meaning into a claim, merely because it suggests how the product wad derived. Applicant further argues that while Applicant agrees that determination of the patentability of a product-by-process claims is based on the product itself; where as here the product resists definition by other than the process by which it is made, the Examiner must recognize that the phrase, "parthogenetically created" gives life and

meaning to the product that necessarily distinguishes it functionally and biochemically from non-parthogenetically created homozygous cells. Thus, the phrase, "parthogenetically created" must be seen, and was intended to mean much more than a production method, but also encompasses a fundamental product-defining characteristics which necessitated its use in the claims' preamble to properly define a product that would be otherwise difficult to define.

Response to Applicant's arguments

The Examiner notes that it is Applicant's burden to demonstrate the products (stem cells) claimed in instant application are different from the products disclosed in the cited prior arts. Applicant's response has failed to provide any distinction between the claimed stem cells and the stem cells disclosed in the prior arts. Applicant asserts that the phrase "parthenogenetically created" breaths life into the claims, however, Applicant fails to support how the product differs in structure from that of the art as a result of such parthenogenetic activation. More elaboration regarding the patentability of the product claimed by product-by-process is provided below.

[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326

(CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972))."

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934.) See MPEP 2113 and MPEP 2112.01.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 95 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's arguments filed 08/10/2007 have been fully considered and they are not persuasive. Previous rejection is ***maintained*** for the reasons of record advanced on pages 3-4 of the office action mailed on 04/10/2007.

Applicant's arguments

Applicant argues that the claim clearly stated that the said cell contains an "identical set" of alleles - meaning that the MH alleles are identical to each other.

Response to Applicant's arguments

The phrase "wherein the stem cell contains an identical set of Major Histocompatibility alleles" recited in claim 92 fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear with regard to at what levels the recited set of Major Histocompatibility alleles being considered as identical to each other. For instance, are the nucleotide sequences of the two copies of every Major Histocompatibility genes in the recited stem cells identical? Or what phenotypes and/or assays are used to define the two alleles being identical.

In this regard, the specification discloses the following relevant, but undefined information: Both homozygous stem (HS) cells with minimal heterozygosity and uniform homozygosity are superior to stem cells with heterozygous ES cells (such as those derived from using fertilized embryonic embryos, therapeutic cloning embryos, and adult stem cells) in that homozygous stem cells can contain *two sets of identical Major Histocompatibility Complex (MHC) haplotypes*. Therefore, immunohistocompatibility matching between a donor and an individual in need of transplantation therapy is easier to achieve with HS cells. Such stem cells homozygous for one MHC haplotype are tolerated not only by recipients carrying the identical haplotype, but also by recipients with the same MHC components in either of their parental haplotypes (See paragraph [0019], US 2002/0168763, publication of instant application).

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 70-73, 75, 80, 82, 84, 90, and 93-95 remain rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al. (Murphy et al., Acute rejection of murine bone marrow

allografts by natural killer cells and T cells. Differences in kinetics and target antigens recognized. *J Exp Med.* 166(5): 1499-509, 1987). Applicant's arguments filed 08/10/2007 have been fully considered and they are not persuasive. Previous rejection is ***maintained*** for the reasons of record advanced on pages 4-5 of the office action mailed on 04/10/2007.

For clarity and completeness of this office action, the rejection of record advanced on pages 4-5 of the office action mailed on 04/10/2007, is reiterated below.

Murphy et al. teach H-2 homozygous bone marrow stem cells harvested from donor mice and a suspension of the cells as allografts were injected to the recipient SCID and BALB/c mice (See abstract, Materials and Methods, and Fig. 3, Murphy et al., 1987).

It is noted that claims 70-73, 75, 80, 82, 84, 90, and 93-95 of instant application are product-by-process claims and the H-2 homozygous bone marrow stem cells taught by Murphy et al. anticipates the pluripotent stem cell homozygous on one or more given haplotype encompassed by the claims of the instant application because the intrinsic structures of the stem cells homozygous on one or more given haplotype are the same. In this regard, applicants attention is drawn to the following statements: When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983), and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d

1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Thus, Murphy et al. clearly anticipates claims 70-73, 75, 80, 82, 84, 90, and 93-95 of instant invention.

Applicant's arguments

With regard to whether Murphy et al. anticipates claims 70-73, 75, 80, 82, 84, 90, and 93-95 of instant invention, Applicant argues that the instant invention serves as a typical example of a situation where a product resists by other than the process by which it is made and it is clearly erroneous for the Examiner to dismiss a phrase which breathes life and meaning into a claim, merely because it suggests how the product wad derived. Applicant further argues that while Applicant agrees that determination of the patentability of a product-by-process claims is based on the product itself; where as here the product resists definition by other than the process by which it is made, the Examiner must recognize that the phrase, "parthogenetically created" gives life and meaning to the product that necessarily distinguishes it functionally and biochemically from non-parthogenetically created homozygous cells. Thus, the phrase, "parthogenetically created" must be seen, and was intended to mean much more than a production method, but also encompasses a fundamental product-defining characteristics which necessitated its use in the claims' preamble to properly define a product that would be otherwise difficult to define.

Response to Applicant's arguments

The Examiner notes that it is Applicant's burden to demonstrate the products (stem cells) claimed in instant application are different from the products disclosed in the cited prior arts. Applicant's response has failed to provide any distinction between the claimed stem cells and the stem cells disclosed in the prior arts. Applicant asserts that the phrase "parthenogenetically created" breaths life into the claims, however, Applicant fails to support how the product differs in structure from that of the art as a result of such parthenogenetic activation. More elaboration regarding the patentability of the product claimed by product-by-process is provided below.

[E]ven though product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798,

802, 218 USPQ 289, 292 (Fed. Cir. 1983).

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972))."

"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934.) See MPEP 2113 and MPEP 2112.01.

5. Claims 70-73, 75, 80, 82, 84, 90, and 93-95 under 35 U.S.C. 102(b) as being anticipated by Opdecamp et al. (Opdecamp et al., Melanocyte development in vivo and in neural crest cell cultures: crucial dependence on the Mitf basic-helix-loop-helix-zipper transcription factor.

Development. 124(12): 2377-86, 1997). Applicant's arguments filed 08/10/2007 have been fully considered and they are not persuasive. Previous rejection is ***maintained*** for the reasons of record advanced on pages 6-7 of the office action mailed on 04/10/2007.

For clarity and completeness of this office action, the rejection of record advanced on pages 6-7 of the office action mailed on 04/10/2007, is reiterated below.

Opdecamp et al. teach *embryos homozygous for a Mitf allele* encoding a non-functional Mitf protein (See abstract, Opdecamp et al., 1997). Opdecamp et al. further teach that (i) neural tube explants were obtained from *Mitf* mutant mouse embryos at E9.5 (15-25 pairs of somites) (See Materials and Methods, Opdecamp et al., 1997), and (ii) the neural crest of vertebrate is a transient population of cells localized in the dorsal portion of the closing neural tube and the cells are remarkably *pluripotent* (See first sentence of Introduction, Opdecamp et al., 1997).

It is noted that claims 70-73, 75, 80, 82, 84, 90, and 93-95 of instant application are product-by-process claims and the pluripotent neural crest cells homozygous for a *Mitf* allele taught by Opdecamp et al. anticipates the pluripotent stem cell homozygous on one or more given haplotype encompassed by the claims of the instant application because the intrinsic structures of the stem cells homozygous on one or more given haplotype are the same. In this regard, applicants attention is drawn to the following statements: When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983), and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Thus, Opdecamp et al. clearly anticipates 70-73, 75, 80, 82, 84, 90, and 93-95 of instant invention.

Applicant's arguments and the Examiner's ***Response to Applicant's arguments*** are the same as discussed in the preceding section of the rejection of claims 70-73, 75, 80, 82, 84, 90, and 93-95 under 35 U.S.C. 102(b) as being anticipated by Murphy et al.

6. Claims 70-73, 75, 80, 82, 84, 90, and 92-95 remain rejected under 35 U.S.C. 102(e) as being anticipated by Sachs et al. (Sachs et al., U.S. Patent No.: 6,469,229, issued date, Oct. 22, 2002). Applicant's arguments filed 08/10/2007 have been fully considered and they are not persuasive. Previous rejection is ***maintained*** for the reasons of record advanced on pages 7-9 of the office action mailed on 04/10/2007.

For clarity and completeness of this office action, the rejection of record advanced on pages 7-9 of the office action mailed on 04/10/2007, is reiterated below.

Sachs et al. teach a swine that is homozygous for a major histocompatibility complex (MHC) haplotype and at least 60% homozygous at all other genetic loci and such animal is propagatable, and a cell or an organ derived therefrom. The invention also provides a method for providing a swine which is homozygous at swine leukocyte antigens (SLA) A, B, C, DR, and DQ, and in which at least 60% of all other genetic loci are homozygous, as well as a method of inducing tolerance in a recipient mammal of a first species to a graft from a donor mammal of a second species (See abstract, Sachs et al., 2002).

Sachs et al. further teach in preferred embodiments, the swine cell is an ***embryonic stem cell***. In other preferred embodiments, the swine cell can be a hematopoietic stem cell, e.g., a cord blood hematopoietic stem cell, a bone marrow hematopoietic stem cell, or a fetal or neonatal liver or spleen hematopoietic stem cell (See lines 25-29, column 2, Sachs et al., 2002).

With regard to stem cell obtained from human (claim 92 of instant application), Sachs et al. teach that in preferred embodiments, the hematopoietic stem cell preparation is from a postnatal animal, e.g., a juvenile or adult animal, or a prenatal animal, e.g., a fetus or an embryo (See lines 35-37, column 3, Sachs et al., 2002), which encompasses stem cell obtained from human recited in claim 92.

It is noted that claims 70-73, 75, 80, 82, 84, 90, and 92-95 of instant application are product-by-process claims and the swine embryonic stem cell homozygous on the MHC haplotype taught by Sachs et al. anticipates the pluripotent stem cell homozygous on one or more given haplotype encompassed by the claims of the instant application because the intrinsic structures of the stem cells homozygous on one or more given haplotype are the same. In this regard, applicants attention is drawn to the following statements: When the reference teaches a

product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983), and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Thus, Sachs et al. clearly anticipates 70-73, 75, 80, 82, 84, 90, and 92-95 of instant invention.

Applicant's arguments and the Examiner's ***Response to Applicant's arguments*** are the same as discussed in the preceding section of the rejection of claims 70-73, 75, 80, 82, 84, 90, and 93-95 under 35 U.S.C. 102(b) as being anticipated by Murphy et al.

Obviousness-type double patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 70-73, 75, 80, 82, 84, 90, 92-95 of instant application No. 09/997,240 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-11, 20, and 21, as amended on 12/18/2006, of the other U.S. application of copending application No. 10/179,959. The copending application No. 10/179,959 is a Continuation-in-part of the instant application No. 09/997,240. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 70-73, 75, 80, 82, 84, 90, 92-95 of instant application No. 09/997,240 are drawn to a

pluripotent stem cell homozygous on one or more given haplotypes, whereas claims 1, 6-11, 20, and 21 of the copending application No. 10/179,959 is drawn to a chromosomally homozygous stem cell obtained from recited methods. The stem cells recited in instant application No. 09/997,240 and the stem cells recited in the copending application No. 10/179,959 are structurally the same and encompassed by each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments and the Examiner's ***Response to Applicant's arguments*** are the same as discussed in the preceding section of the rejection of claims 70-73, 75, 80, 82, 84, 90, and 93-95 under 35 U.S.C. 102(b) as being anticipated by Murphy et al.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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